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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,224	07/30/2001	David A. Sanders	7024-497PUR115	2859

26813 7590 08/26/2004

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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/762,224

Applicant(s)

SANDERS ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 13-18, 30-32, 39, 44-52, 54 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 19-29, 33-38, 40-43 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Serial No.: 09/762,224  
Applicants: Sanders, D. A., et al.

Docket No.: 7024-497P  
Filing Date: 07/30/01

### Detailed Office Action

#### *Status of the Claims*

Acknowledgement is hereby made of receipt and entry of the amendment filed 19 May, 2004. Claims 1-12, 19-29, 33-38, 40-43, and 53 are currently under examination. Claims 13-18, 30-32, 39, 44-52, 54, and 55 stand withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

#### *35 U.S.C. § 120/119*

Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119(e) as follows: This application was not filed within twelve months from the filing date of the provisional application, and there is no indication in the first paragraph of the specification of an intermediate nonprovisional application that is directly claiming the benefit of the provisional application and filed within 12 months of the filing date of the provisional application. It is noted that this application is a national stage application of PCT/US99/17702. If applicant desires priority based upon a National Stage filing, this information should also be referenced in the first sentence of the specification (i.e., **This application is a National Stage entry of International Application No. PCT/CCPY/NNNNN, filed , 199N**). Appropriate correction is required.

#### *35 U.S.C. § 112, Second Paragraph*

Claims 1-12, 19-29, 33-38, 40-43, and 53 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements

are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Claims 1-12, 19-29, 40-43, and 53, all remain vague and indefinite for failing to clearly set forth the salient characteristics of the nucleic acid construct(s) and expression vectors. The claims all suffer from the same deficiencies. Applicants traverse and submit that the claim language is clear and definitive. This argument is clearly not persuasive. Claim 1 still simply recites a eukaryotic cell comprising a first, second, third, and fourth nucleotide sequence. However, the claims fail to provide sufficient structural and functional limitations to enable the skilled artisan to ascertain the metes and bounds of the claimed invention. For instance, are the four nucleotide sequences tandemly arranged on a single plasmid-based expression vector? If this vector was transfected into a cell line, multiple copies of it and each of the corresponding genes would be present. Alternatively, are the coding portions present on four different expression vectors that are designed to provide greater safety against recombinatorial events. Moreover, what type of expression vector is currently being employed? Are the sequences encoded by different retroviral expression vectors? If so, what are the salient characteristics of each vector? The claims also fail to provide a functional nexus for the four nucleotide sequences. What purpose do these sequences serve when transfected/transduced within a cell? Are the claims actually directed toward a RVVP-producing cell line? Do the claims encompass transient or stable RVVP-producing cell lines? The claims clearly fail to meet the requirements of 35 U.S.C. § 112, second paragraph. Appropriate correction, as supported by the disclosure, is required.

Applicants are directed toward Examples 2-4 for further guidance in drafting the claim language.

Claims 19-29 are further vague and indefinite since the preamble is illogical. The claim is directed toward a "method of forming a eukaryotic cell" which is confusing. The methodology steps do not result in the formation of a cell. Instead the parent cell line is transfected with appropriate RVVP constructs that enable the existing cell line to produce RVVPs. The expression constructs provide various features in trans that results in the production of retroviral particles. The transfected constructs may result in transient expression or stable expression of said proteins. The method steps are further confusing since they simply recite transfecting a cell with various nucleotide sequences. How does this result in the production of a stable cell line capable of producing pseudotyped retroviruses? There is no nexus between the preamble, method steps, and final conclusion. Applicants are again directed toward the specification for further guidance in drafting the claim language.

Claims 40-43 suffer from the same deficiencies set forth above. Moreover, the reference to a "selected ribonucleotide sequence" remains vague and indefinite. What are the structural and functional characteristics of this "selected" sequence. For instance, does it encode a selectable marker, a diagnostic marker, another structural gene, a ribozyme, or antisense molecule? Applicants need to clearly and unambiguously set forth the salient characteristics of the claimed sequence.

### ***35 U.S.C. § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 19-29, 33-38, 40-43, and 53 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Rochester*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004). The claims are directed toward poorly and vaguely defined RVVPs, cell lines capable of producing said particles, and methods for producing said cell lines.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of RVVPs, producer cell lines, and methods of making said products.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic,

without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the


capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The disclosure vaguely describes the preparation of pseudotyped retroviral vector particles wherein the Gag and Pol genes were provided by MoMLV expression constructs and the Env coding functions were provided by RRV E<sub>3</sub> and E<sub>2</sub> glycoproteins. The disclosure does not describe any additional expression systems (i.e., lentiviral), viral envelope glycoproteins (with the exception of an Ebola Env construct which is also poorly described), expression systems employing four different expression vectors, or "selected" ribonucleotide sequences. Thus, the skilled artisan would reasonably conclude that applicants were in possession of a recombinant MoMLV expression system that was capable of producing RRV-pseudotyped RVVPs. However, the skilled artisan would also not conclude that applicants were in possession of a sufficient number of recombinant RVVPs to support the broad genus of compounds currently encompassed by the claim language.

*Correspondence*

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

22 August, 2004